Exhibit 13

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August 7, 2019

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Re: *In re Valsartan Products Liability Litigation*
USDC, District of New Jersey, No. 1:19-md-02875-RBK-JS

Dear Counsel:

In accordance with Case Management Order No. 10 (Dkt. 141), I write in response to your letter of July 31, 2019, describing purported deficiencies in Mylan Pharmaceuticals Inc.'s ("Mylan") core discovery production. I will address the five Mylan-specific issues in the order in which you have listed them.

1. ANDA 204743

This litigation centers upon Plaintiffs' allegation that they "purchased or used generic formulations of valsartan medications containing the nitrosamine impurities," thereby causing harm—be it, economic or physical. (Dkt. 1, Tr. Or., at 2.) When the Court limited core discovery to the "products at issue in the litigation," Dkt. 88, Or., at ¶ 2, it necessarily meant those valsartan-containing medications that were *purchased* or *used* by Plaintiffs. As you observe, Mylan submitted, but the FDA has not yet approved, ANDA 204743 relating to amlodipine, valsartan, and hydrochlorothiazide tablets. Given that Mylan does not market this product, it follows that Plaintiffs could not have purchased, used, or been harmed by it. ANDA 204743 is therefore beyond the scope of core discovery. (*See* Dkt. 88, Or., at 1 n.1 [noting that core discovery is limited to "unquestionably relevant" materials].)

Your statement that this ANDA was "deni[ed]" as a result of "contamination issues" is incorrect. The document you reference, MYLAN-MDL2875-00029879, makes clear that ANDA 204743 remains pending, but FDA was not in a position to approve the application until it obtains additional information from the DMF-holder, Mylan Laboratories Ltd. In any event, Mylan *has* produced communications with FDA relating to the valsartan recalls, the investigation into the cause of the alleged impurities, and efforts to detect and remove the impurities—regardless of whether those documents relate to the pending ANDA 204743 or Mylan's three approved ANDAs. Core discovery is intended to offer Plaintiffs insight as to how the impurities arose during the API manufacturing process. Production of additional documents relating to ANDA 204743 concerning a finished-dose product that has never been sold in United States would not further that purpose.

2. TESTING DOCUMENTS

You suggest that Mylan failed to comply with ¶ 6(a)(3)(2) of the Court's core discovery order, but you offer nothing in support of the assertion. The section you cite requires the production of communications with FDA relating to "the investigation into the cause of the alleged contamination." Mylan has done so. As you note, among the nearly 100,000 pages of information Mylan produced on June 27 were data reflecting testing results based on API batch numbers. You then submit what is, in essence, a Rule 34 request for production of a "corresponding document identifying results based on US NDC code/lot number." You insist that, otherwise, Mylan must "confirm that no such document exists."

This is precisely the sort of demand the Court repeatedly rejected during the meet-and-confer process. (*See, e.g.*, 4/10/19 Tr., at 28:22 [noting that what are, in essence, Rule 34 requests for production fall beyond the scope of core discovery].) And nothing in Judge Schneider's orders obligates Mylan to identify with pinpoint precision a particular sub-subcategory of documents that may or may not exist within its core discovery production. I will, however, state that I am not presently aware of the existence of a "corresponding document identifying results based on US NDC code/lot number" within those materials produced thus far by Mylan. Nonetheless, I would direct your attention to the email produced at MYLAN-MDL2875-00029397–29401 and its related attachments, from which you should be able to derive the information you are demanding.

3. FACILITY INSPECTION REPORTS

Simply put, Mylan has complied with ¶ 6(a)(3)(5) by producing "all FDA Form 483's, Establishment Inspection Reports, CGMP inspection reports, and warning letters, as well as the responding defendants' responses to same, regarding any facility ***that manufactured or supplied the API at issue***" from 2010 to present. The two facilities where Mylan Laboratories Ltd. has manufactured valsartan API were identified in my correspondence of June 27, 2019. The majority of the relevant documents was produced on July 19, 2019, with a small supplement on July 30 reflecting more recent correspondence. (*See generally* MYLAN-MDL2875-00030084–30969.)

You take issue with the fact that Mylan has not provided documents concerning FDA's inspections of facilities in Nashik and Morgantown. Mylan manufactures valsartan-containing finished-dose medications at: (i) Nashik, India (FEI No. 3005587313); (ii) Aurangabad, India (FEI No. 3008316970); and (iii) Morgantown, West Virginia (FEI No. 1110315). (*See* MYLAN-MDL2875-00029386.) These facilities, however, did not manufacture or supply the API at issue. Therefore, pursuant to both the plain language of the Court's core discovery order and the frequent acknowledgments in Plaintiffs' master complaints and elsewhere that the alleged impurities arose during the API manufacturing process, Mylan was not required to produce Nashik and Morgantown materials at this stage.

The purpose of this meet-and-confer process is to evaluate whether Mylan has produced the documents identified in the Court's core discovery order, not some overarching inquiry of what might be somehow "relevant" in the context of this litigation. Thus, you miss the mark when you argue that Mylan's production was deficient because the Nashik and Morgantown facilities are referenced in the ANDA files and "played critical roles" in the manufacture of "Valsartan products"—but, notably, *not* the "API at issue." (Dkt. 88, Or., ¶ 6(a)(3)(5).) What you do not say, and what you cannot say, is that the core discovery order obligated Mylan to produce documents relating to FDA's inspections of facilities other than those that manufactured valsartan API.

4. CUSTOMER LIST

Pursuant to ¶ 6(a)(3)(6), API manufacturers were required to produce "[c]ommunications with the FDA relating to . . . a list of all United States customers from 2010 to present." I am not aware of the existence of any such communications. Even so, in my correspondence of June 27, I provided a list of all entities which, from 2010 to present, purchased valsartan API from Mylan Laboratories Ltd. potentially to be used in finished dosage forms intended for the United States market. Frankly, that is more than the core discovery order required.

In your letter, you imply that Mylan must produce a separate list of its finished-dose customers dating back to the approval of its valsartan hydrochlorothiazide product in 2012. There are at least two problems with your position. First, ¶ 6(a)(3)(6) relates to API manufacturers, not finished-dose manufacturers. Mylan has provided a list of its API customers, and your demand for additional information falls outside the scope of the core discovery order.

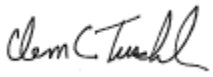
Second, you presuppose that Mylan has an independent duty—akin to a Rule 33 interrogatory—to compile a list of finished-dose customers. Again, the Court has emphasized that core discovery is not merits discovery. (*See* 4/10/19 Tr., at 31:10–14.) Judge Schneider's order requires the production of communications with FDA relating to API customer lists. Though outside the scope of the order, you acknowledge that Mylan has also produced communications relating to finished-dose customers, including an all-encompassing list of consignees who received recalled product. (*See* MYLAN-MDL2875-00029158.) I am not aware of any instance where Mylan provided FDA with a list of all finished-dose customers dating back to 2012. And even in the context of merits discovery, a "party 'cannot be compelled to create . . . documentary evidence which is not already in existence in some form.'" *Graco, Inc. v. PMC Glob., Inc.*, No. 3:08-cv-1304, 2011 WL 1114233, at *37 (D.N.J. Mar. 24, 2011) (quoting *Rockwell International Corp. v. H. Wolfe Iron & Metal Co.*, 576 F. Supp. 511, 513 (E.D. Pa. 1983)); *accord* 8B Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2210 (3d ed.).

5. ESI DEFICIENCIES

As you note, Mylan has produced documents which contain .xsl, .xml, .joboptions, .dtd, and .txt file extensions. In response to your letter, Mylan reviewed its production and can confirm that these file types were properly produced in accordance with the ESI protocol.

As always, I remain willing to continue the meet-and-confer process should you have any outstanding questions or concerns. If you wish to do so, please let me know your availability for a teleconference before next week's hearing with Judge Schneider.

Very truly yours,



Clem C. Trischler